United States District Court,
N.D. California.

GENERAL ATOMICS, DIAZYME, LABORATORIES DIVISION,
Plaintiff.
v.
AXIS-SHIELD ASA,
Defendant.

No. C 05-04074 SI

July 19, 2006.

Background: Company filed action against competitor seeking declaratory judgment that its products, enzymic homocysteine assays that detected the level of homocysteine in human samples, did not infringe competitor's method patents. Company moved for summary judgment of noninfringement.

Holdings: The District Court, Illston, J., held that:
(1) company's products did not literally infringe competitor's patents, and
(2) company's products did not infringe competitor's patents under the doctrine of equivalents.

Motion granted.

5,631,127, 5,958,717. Not Infringed.

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Elaine Y. Chow, Timothy P. Walker, Preston Gates Ellis LLP, San Francisco, CA, Louis Chip Cullman, Preston Gates & Ellis, Irvine, CA, Paul C. Nyquist, Newport Beach, CA, for Defendant.

ORDER GRANTING PLAINTIFF'S, MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

ILLSTON**, District Judge.**

On June 2, 2006, the Court heard argument on plaintiff's motion for summary judgment of noninfringement. Having considered the arguments of counsel and the papers submitted, and for good cause appearing, the Court hereby GRANTS plaintiff's motion.

BACKGROUND

Plaintiff General Atomics is a California corporation that sells enzymic homocysteine assays that detect the level of homocysteine in human samples. FN1 On October 11, 2005, General Atomics filed this action against Axis-Shield ASA, a Norwegian corporation, seeking a declaratory judgment that its assays did not infringe U.S. Patents owned by Axis Shield. Although the complaint originally sought a declaration of non-infringement as to four Axis-Shield patents, only two remain in this suit: U.S. Patent No. 5,631,127 ("the '127 patent"); and U.S. Patent No. 5,958,717 ("the '717 patent").

FN1. Homocysteine is a naturally occurring amino acid found in the human body. Elevated levels of homocysteine can signify cardiovascular disease, Alzheimer's, and osteoporosis. *See* Borchardt Decl., para. 19.

The parties are in general agreement as to the means by which General Atomics' homocysteine assay functions.FN2 To measure the level of homocysteine in a sample, General Atomics' assay involves adding a co-substrate called S-adenosyl-L-methionine ("SAM") to the sample. An enzyme that acts on both the homocysteine and SAM is then added. This enzyme, referred to as "HMTase," removes a methyl group from the co-substrate SAM and attaches it to the homocysteine, converting the homocysteine into methionine and the SAM into S-adenosyl-L-homocysteine ("SAH"). The SAH, after amplification, is then measured on an automated chemical analyzer. General Atomics claims that this assay is an improvement over prior technologies because it does not involve chromatography or the use of antibodies, both of which add complications to the procedure.

FN2. General Atomics' motion for summary judgment concerns only the product it currently sells. It does not move for summary judgment on the other accused product, which it formerly sold but no longer makes.

Axis-Shield contends that General Atomics' assay infringes both the '127 patent and the '717 patent. These patents are directed towards methods for detecting levels of homocysteine in samples of blood, plasma, or urine, as well as kits for performing those methods. The patents both stem from the same priority application, and have substantially identical specifications. General Atomics claims that its assay does not infringe claim 1 of either patent. All asserted claims depend on claim 1 of the '127 patent or claim 1 of the '717 patent.FN3

FN3. Both claims at issue are written in "Jepson" format, in which the independent claims contain three parts: "(1) a preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known, (2) a phrase such as 'wherein the improvement comprises,' and (3) those elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion." 37 C.F.R. s. 1.75(e); *see also* Rowe v. Dror, 112 F.3d 473, 479 (Fed.Cir.1997).

Claim 1 of the '127 patent reads as follows:

In a method for assaying homocysteine in a sample, said method comprising the steps of (i) contacting said

sample with a homocysteine converting enzyme and at least one substrate for said enzyme other than homocysteine, and (ii) assessing an analyte which is a substrate for said enzyme, wherein the improvement comprises in step (i) contacting said sample with said substrate other than homocysteine and in step (ii) without chromatographic separation assessing a non-labelled analyte selected from the group consisting of a homocysteine co-substrate and the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme.

'127 patent, 22:44-55. Claim 1 of the '717 patent is similar, and provides:

In a method for assaying homocysteine in a sample, said method comprising the steps of (i) contacting said sample with a homocysteine-converting enzyme and (ii) assessing an analyte, wherein the improvement comprises in step (ii) without chromatographic separation assessing a non-labeled analyte selected from the group consisting of the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme.

'717 patent, 22 :60-67.

General Atomics now moves for summary judgment, claiming that the undisputed facts show that its assay does not infringe claim 1 of either the '127 or ' 717 patent. The Court agrees.

LEGAL STANDARD

I. Summary Judgment

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *See* Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). The moving party, however, has no burden to negate or disprove matters on which the non-moving party will have the burden of proof at trial. The moving party need only point out to the Court that there is an absence of evidence to support the non-moving party's case. *See* id. at 325.

The burden then shifts to the non-moving party to "designate 'specific facts showing that there is a genuine issue for trial.' " Id. at 324 (quoting Fed.R.Civ.P. 56(e)). To carry this burden, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). "The mere existence of a scintilla of evidence ... will be insufficient; there must be evidence on which the jury could reasonably find for the [non-moving party]." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

In a motion for summary judgment, the evidence is viewed in the light most favorable to the non-moving party, and all justifiable inferences are to be drawn in its favor. Id. at 255. "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge [when she] is ruling on a motion for summary judgment." *Id*.

II. Claim construction

[1] [2] [3] [4] [5] [6] Claim construction is a matter of law. Markman v. Westview Instr., Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Terms contained in claims are "generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id*. In determining the proper construction of a claim, a court begins with the intrinsic evidence of record, consisting of the claim language, the patent specification, and, if in evidence, the prosecution history. *Id* at 1313. "The appropriate starting point ... is always with the language of the asserted claim itself." Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998). "[T]he language of the claim frames and ultimately resolves all issues of claim interpretation." Abtox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed.Cir.1997). In the absence of an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning. However, claims are always read in view of the written description. *See* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996).

[7] [8] [9] The written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format. SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1344 (Fed.Cir.2001). In other words, the specification may define claim terms "by implication" such that the meaning may be "found in or ascertained by a reading of the patent documents." Vitronics, 90 F.3d at 1584 n. 6. Although claims are interpreted in light of the specification, this "does not mean that everything expressed in the specification must be read into all the claims." Raytheon Co. v. Roper Corp., 724 F.2d 951, 957 (Fed.Cir.1983). For instance, limitations from a preferred embodiment described in the specification generally should not be read into the claim language. *See* Comark, 156 F.3d at 1187. However, it is a fundamental rule, that "claims must be construed so as to be consistent with the specification." Phillips, 415 F.3d at 1316. Therefore, if the specification reveals an intentional disclaimer or disavowal of claim scope, the claims must be read consistent with that limitation. *Id*.

[10] Although not as persuasive as intrinsic evidence, a court may also rely on extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," to determine the meaning of claim language. Phillips, 415 F.3d at 1317. All such extrinsic evidence should be evaluated in light of the intrinsic evidence. Id. at 1319.

DISCUSSION

As mentioned above, General Atomics asserts that its assay does not infringe claim 1 of the '127 patent or claim 1 of the '717 patent. Both of these claims are the only independent claims in their respective patents. Thus, if General Atomics is correct, it is entitled to summary judgment of noninfringement. *See* Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed.Cir.1989) ("It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to have been infringed.").

General Atomics raises three arguments in support of its contention that its assay does not infringe the patents at issue. The Court considers each in turn.

I. "Assessing an Analyte which is a Substrate for Said Enzyme"

[11] [12] The preamble to claim 1 of the '127 patent describes the second step of the invention as "assessing an analyte which is a substrate for said enzyme." The parties appear to agree that the term "analyte" means

"a chemical compound that is the subject of a chemical analysis." *See* Aannestad Decl., Exh. 5. In the case of General Atomics' assay, the analyte is SAH because that is what is measured at the end of the reaction. The parties also appear to agree that the term "substrate" means "the substance on which an enzyme acts to form a product." *See* Borchardt Decl., para. 27. In General Atomics' assay, the only substrates are homocysteine and SAM. Finally, "said enzyme" refers to the "homocysteine converting enzyme" mentioned earlier in the claim. In the case of General Atomics' assay, "said enzyme" is HMTase. Under these definitions, it is undisputed that General Atomics' assay does not "assess[ ] an analyte which is a substrate for said enzyme," because SAH (the analyte) is not a substrate for HMTase (the homocysteine conversion enzyme). FN4

FN4. According to Axis Shield, it is possible that SAH is a substrate for HMTase. Certain enzymic reactions are "reversible," meaning that they can convert substrates to products and also can convert those products back to the original substrates. A reaction disclosed in the patents at issue has this characteristic; the enzyme SAH-hydrolase converts homocysteine and adenosine into SAH, but also converts SAH into homocysteine and adenosine. *See* '127 patent, 3 :39-47.

Based on the above, Axis Shield requests further time to determine whether the reaction in General Atomics' assay is reversible, in which case SAH would be a substrate of HMTase. The Court declines this request for two reasons. First, Axis Shield has failed to make any specific showing of tests it has conducted or tests it plans on performing to determine if the reaction is reversible. Instead, it has merely asserted that "all chemical reactions are reversible in principle." Def. Oppo. Br. at 26. While the Court is sympathetic to Axis Shield's claims that it has not yet had the opportunity to depose General Atomics' experts, Axis Shield's request is based on nothing more than speculation. Without a more specific showing, the Court will not grant Axis Shield's request based on the theoretical possibility that the HMTase reaction is reversible. *See* Borchardt Decl., para.para. 30-32 (discussing paper from 1964 that was unable to show that HMTase reaction was reversible). Second, as the Court finds below that SAH is neither a co-substrate of homocysteine nor a "homocysteine conversion product," summary judgment is appropriate regardless of whether SAH is a substrate of HMTase.
Because it is clear that SAH is not a substrate for HMTase, the parties dispute the precise impact that the preamble language in a Jepson claim has on the scope of the invention. General Atomics argues that the preamble is a claim limitation that must be met. Axis Shield, on the other hand, argues that the preamble conflicts with the more specific description of the patents' improvements that occurs later in the claim. In such circumstances, Axis Shield argues, the more specific description of the improvement should control.

The Court agrees with Axis Shield that claim 1 of the '127 patent is internally inconsistent. While the preamble describes the analyte as a "substrate," the improvement portion of claim 1 expands the class of analytes to include "the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." '127 patent, 22 :53-55. As "homocysteine conversion products" are the products of, not the reagents used in, the reaction, in most cases it appears that "homocysteine conversion products" will not be substrates of the enzyme used in the reaction.FN5 Thus, the inclusion of "substrate" creates an inconsistency within the patents' claims by limiting the "improvement" portion in a manner that does not seem entirely logical.

FN5. Due to the presence of "reversible" reactions, there is the possibility that some analytes will be both substrates and products of a given enzyme.

[13] General Atomics attempts to avoid this inconsistency by arguing that the Federal Circuit has already addressed this question. While ordinarily a claim preamble does not limit the scope of the claimed invention, the preamble in a Jepson claim is a claim limitation that helps define the scope of the claimed invention. Rowe v. Dror, 112 F.3d 473, 479 (Fed.Cir.1997) ("When [the Jepson] form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope."); *see also* Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029 (Fed.Cir.2002) ("[T]he fact that the patentee has chosen the Jepson form of the claim evidences the intention 'to use the preamble to define, in part, the structural elements of his claimed invention.' Thus, the preamble is a limitation in a Jepson-type claim."); Manuel of Patent Examining Procedure s. 608.01(m) ("The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as a part of the claimed combination."). Especially given the "public notice" function of a patent, it seems fairest to read any contradictionin a patent's claims against the patent holder. *Cf.* Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed.Cir.1996) ("[W]here there is an equal choice between a broader and a narrower meaning of a claim ... the notice function of the claim [is] best served by adopting the narrower meaning."). Further, the "substrate" limitation does not appear in the '717 patent, suggesting that the language plays some role in the '127 patent.

General Atomics' argument, however, is not entirely convincing. None of the cases cited by General Atomics involved preambles that were inconsistent with the improvements disclosed in a Jepson claim. *See* Rowe v. Dror, 112 F.3d 473, 479 (Fed.Cir.1997) (finding that "balloon angioplasty catheter" in preamble to claim was structural limitation); Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1029 (Fed.Cir.2002) (finding that preamble that described method for "providing gas assistance to a resin injection molding process" did not restrict claim to "apparatuses and methods that perform complete injection molding processes"). Where, as here, a Jepson claim's preamble is written in a way that seems to contradict the description of the invention's improvement over the prior art, there is certainly an argument that the description of the improvement should control, as that is what constitutes the invention. *Cf.* Pause Tech., LLC v. TiVo, Inc., 419 F.3d 1326, 1331 (Fed.Cir.2005) (rejecting argument that "[r]egardless of what claim language appears in a later portion of the claim, that language should not be read into the interpretation of a separate claim element"). Indeed, the federal regulations only require the preamble to contain a "general description" of the prior art, not the type of detailed limitations that are ordinarily found in patent claims. *See* 37 C.F.R. s. 1.75(e).

It is unclear to the Court the precise manner in which the preamble limits the scope of the claimed invention here. Ultimately, the Court need not decide this novel issue. Both parties agree that even if the Court were to accept Axis Shield's argument and were to rule that "substrate" did not limit the patents' claims, General Atomics' assay would also have to meet both the "homocysteine co-substrate" and the "homocysteine conversion products" claim limitations discussed below. As the Court finds that General Atomics' assay does not contain either of these limitations, it declines to reach the question of how the use of "substrate" in the preamble limits the '127 patent's scope.

II. "Assessing a Non-Labelled Analyte Selected from the Group Consisting of a Homocysteine Co-Substrate and the Homocysteine Conversion Products of the Enzymic Conversion of Homocysteine"

In order to infringe claim 1 of the '127 patent, General Atomics' assay must assess one of two analytes: "a homocysteine co-substrate" or "the homocysteine conversion products of the enzymic conversion of homocysteine." Claim 1 of the '717 patent requires only an assessment of the latter analyte to infringe. The Court agrees with General Atomics that its assay does not contain either of these limitations.

A. "Assessing ... a Homocysteine Co-Substrate"

[14] The specification of the '127 patent defines "homocysteine co-substrate" as "a compound which reacts with homocysteine in the enzyme-catalysed, e.g. a SAH-hydrolase catalysed, homocysteine conversion reaction." '127 patent, 2 :43-45. Axis Shield argues that this definition indicates that "homocysteine co-substrate" is not limited to the specific co-substrate used in a particular assay, but that it may be a homocysteine co-substrate for any conceivable enzymic reaction that uses homocysteine as a substrate. For example, Axis Shield argues that SAH, which is not a homocysteine co-substrate in the General Atomics assay, nonetheless constitutes a homocysteine co-substrate under claim 1 of the '127 patent because there may be other enzymic reactions in which SAH acts as a homocysteine co-substrate.

The Court rejects Axis Shield's proposed construction of homocysteine co-substrate. The passage quoted above makes clear that "homocysteine co-substrate" is specific to the enzyme used, and is not any potential co-substrate of homocysteine. Indeed, in its proposed construction Axis Shield changes "*the* enzyme catalyzed ... homocysteine conversion reaction" to "*an* enzyme catalyzed homocysteine conversion reaction." Def. Oppo. Br. at 15. Axis Shield provides no reason why this change is warranted by the specification. Accordingly, the Court adopts General Atomics' proposed construction of "homocysteine co-substrate": "a compound which reacts with homocysteine in the homocysteine conversion reaction of the assay."

Because General Atomics' assay assesses SAH, which is not a co-substrate of homocysteine in the HMTase reaction, the Court finds that the assay does not contain the claim limitation "assessing ... a homocysteine co-substrate." FN6

FN6. In any event, Axis Shield has provided no evidence that SAH is a co-substrate of homocysteine in any reaction. It has therefore failed to meet its burden even under its own construction of "homocysteine co-substrate." *See* Borchardt Reply Decl., para.para. 7-8 (stating that he is aware of no reaction in which SAH is a co-substrate of homocysteine).

B. "Assessing ... the Homocysteine Conversion Products of the Enzymic Conversion of Homocysteine"

Claim 1 of both the '127 patent and the '717 patent includes the step of "assessing ... the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme." Axis Shield argues that General Atomics' assay contains this claim limitation. Alternatively, it argues that even under General Atomics' construction of the phrase, the assay infringes under the doctrine of equivalents.

1. Proper Construction

[15] The dispute over the meaning of "homocysteine conversion products of the enzymic conversion of homocysteine" centers on whether "homocysteine conversion products" must be the products of the enzymic reaction that derive specifically from homocysteine, or whether they include all products of the homocysteine conversion reaction. Axis Shield argues that the term includes all of the products of the enzymic reaction, including the products that derive from the homocysteine co-substrate. General Atomics, on the other hand, argues that "homocysteine conversion products" are limited to the "conversion products derived from homocysteine in the reaction catalyzed by the homocysteine converting enzyme of the assay." *See* Borchardt Decl., para. 36. Under General Atomics' interpretation, its assay would not infringe because

the only "homocysteine conversion product" of the HMTase reaction is methionine; SAH is a conversion product of SAM, not homocysteine.

The Court agrees with General Atomics that the plain language of the claims limits "homocysteine conversion products" to those products of the homocysteine conversion reaction that are derived from homocysteine. The claims at issue clearly state that the reaction products to be assessed are "products of the enzymic conversion of homocysteine." Elsewhere, the specification generally uses "homocysteine conversion reaction" or just "reaction" to refer to the reaction as a whole; the more narrow language of the claims does not appear. *See, e.g.,* '127 patent, 2 :45 ("homocysteine conversion reaction"); 2:59-63 (referring to "direct or indirect reaction product of the enzymic conversion of the analyte"); 3:3-4 ("[SAH-hydrolase] catalyses the homocysteine reaction"). Even the claims of the ' 127 patent use the language "homocysteine conversion reaction." Id. at 24:6-12. Aside from the abstract, the closest the specification comes to the language at issue is "products of the enzymic conversion of homocysteine," language not as limited as that found in the patents' claims. *See* '127 patent, 2 :29-30; *see also* ' 127 patent, 12 :39-42. The specification therefore demonstrates that Axis Shield chose narrower language for its claimed invention than the language it had available to it. The Court finds that, by limiting the analyte to the "homocysteine conversion products of the enzymic conversion of homocysteine," the patents' claims confine the possible analytes to those that derive from homocysteine itself, not those that derive from the reaction generally.

Axis Shield disagrees with this reading of the '127 patent, and argues that the plain language of the claims indicates that "homocysteine conversion products" may be any products of the conversion reaction. This argument is difficult to follow, but Axis Shield apparently argues that the phrase "of the enzymic conversion of homocysteine by said enzyme" modifies both "homocysteine co-substrate" and "homocysteine conversion products." Under this reading, Axis Shield argues that the phrase "of the enzymic conversion of homocysteine by said enzyme" means "associated with the enzyme-catalyzed homocysteine reaction." Oppo. Br. at 16. The Court finds this reading of the claim language strained; referring to a co-substrate *of* a reaction is awkward phrasing, at best. The patents do not use such language to modify "homocysteine co-substrate" in other areas of their specifications. *See, e.g.,* '127 patent, 3 :11 ("In the above scheme, adenosine is the homocysteine co-substrate."). Rather, the specifications refer to co-substrates in the manner identified by General Atomics' expert. *See* Borchardt Reply Decl., para. 10 ("The correct way to identify a co-substrate is to name another substrate with which it reacts."). In addition, other claim language refers to a "substrate ... *for* the homocysteine conversion reaction," a much more sensible method of referring to the substrate than "a homocysteine co-substrate ... *of* the enzymic conversion of homocysteine." *See* '127 patent, 24 :9-10 (emphasis added). Thus, the Court rejects Axis Shield's argument that "enzymic conversion of homocysteine" modifies both "homocysteine conversion products" and "homocysteine co-substrate," and that the phrase should therefore mean "associated with the enzyme-catalyzed homocysteine reaction."

Axis Shield also raises a number of arguments against General Atomics' construction of "homocysteine conversion products." First, it points to a single disclosure in the patents' specifications that refers to using the "products of ... [homocysteine conversion] reactions ... as analytes." *See* ' 127 patent, 4 :5-8 ("The co-substrates and the conversion products of these various reactions may be used as the analytes in the assay of the invention."). Axis Shield argues that this disclosure indicates that the patent was not intended to be limited to assessing products derived from homocysteine.FN7 This single disclosure,however, unlimited by the more specific phrasing of the patent's claims, only serves to demonstrate language that would have achieved Axis Shield's proposed construction. Instead of referring to the products of the "homocysteine conversion reaction," however, the claims limit their reach to "homocysteine conversion products of the enzymic conversion of homocysteine." Further, read in context, the quoted language was not intended to

specify the scope of the invention. Rather, it was a reference to a number of homocysteine conversion reactions documented in the scientific literature, establishing the possibility that those reactions could be utilized in the invention. The Court finds that the above disclosure in the specification is insufficient to broaden the plain meaning of the claim terms. *See* SuperGuide Corp. v. DirecTV Enters., 358 F.3d 870, 875 (Fed.Cir.2004) ("The written description, however, is not a substitute for, nor can it be used to rewrite, the chosen claim language.").

FN7. Another portion of the specification contains language more similar to, but arguably broader than, the claim language: "In one aspect the present invention therefore provides a method for assaying homocysteine in a sample, said method comprising the steps of ... assessing (preferably photometrically) a non-labelled analyte selected from the homocysteine co-substrate and the products of the enzymic conversion of homocysteine by said enzyme." '127 patent, 2 :21-31.

Axis Shield also argues that General Atomics' construction is inconsistent with a number of embodiments disclosed in the specification. The first such embodiment is a betaine reaction in which an enzyme named BHMase converts homocysteine and betaine into methionine and dimethylglycine. ' 127 patent, 2 :38-39; Green Decl., para.para. 10-11. Because the enzyme in this reaction transfers a methyl group from the betaine to the homocysteine, the enzyme effectively acts in an identical manner as the HMTase in General Atomics' assay. Thus, Axis Shield argues that its patent should be read broadly enough to cover similar reactions.

Setting aside the fact that the patents only contain cursory references to the betaine reaction, Axis Shield's argument fails because there is no indication of how the assessment of the betaine reaction is performed. Indeed, the patents' specifications reference the betaine reaction in conjunction with a number of other potential enzymic reactions then state simply, "[t]he co-substrates and the conversion products of these various reactions may be used as the analytes in the assay of the invention." '127 patent, 4 :5-10. There is no indication that dimethylglycine should be used as the analyte; if betaine were used as the analyte the reaction would fall within the patents' scope. Thus, the Court does not believe that its construction of "homocysteine conversion products" removes the betaine reaction from the reach of the patents' claims.

A second embodiment that Axis Shield argues this Court's construction overlooks is the disclosure of a method for "indirect assessment" of the analyte. The patents teach that "the chemical species actually detected need not of course be the analyte itself but may for example be a derivative thereof or some further substance." '127 patent, 2 :52-55. Because the patents teach detecting a substance other than a homocysteine conversion product, Axis Shield argues, there is no need to limit the analyte to those reaction products that were derived from homocysteine. This argument misses the point, however; it is not what is ultimately detected that is important to the patent, it is the method of measuring homocysteine by assessing the level of homocysteine-derived products in the sample. Indirect assessment still operates in this same basic manner.

The final embodiment that Axis Shield contends is excluded by this Court's construction of "homocysteine conversion products" is the "inhibition" embodiment in the specification. The inhibition embodiment measures the level of homocysteine in a sample by adding the enzyme SAH-hydrolase and either adenosine and SAH. SAH-hydrolase is an enzyme that creates a reversible reaction; it converts SAH into homocysteine and adenosine, and also converts homocysteine and adenosine back into SAH. Thus, the level of homocysteine in a sample can be monitored either by adding adenosine or SAH. If adenosine is added, the SAH hydrolase creates SAH from the adenosine and homocysteine, allowing the level of homocysteine

to be determined by monitoring the decrease of adenosine in the sample. If SAH is added, the enzyme acts to split it into homocysteine and adenosine. Because the reaction is reversible, however, "any homocysteine present in the test sample will counteract this net reaction, and thus inhibit the formation of adenosine." '127 patent, 3 :48-55. By monitoring the increase in the level of adenosine formed in the sample, one can therefore determine the amount of homocysteine. *Id*.

[16] Neither of these embodiments is excluded from the claims of the '127 patent by General Atomics' construction because they involve assessing adenosine, a co-substrate of homocysteine for the SAH-hydrolase enzyme.FN8 Both embodiments, however, are excluded from the claims of the ' 717 patent, because the analyte disclosed is adenosine. Even under Axis Shield's construction of the term, adenosine is not a "homocysteine conversion product" because it is not a product of the homocysteine conversion reaction; it is a product only of the conversion of SAH. Thus, the inhibition embodiments are simply unclaimed subject matter, and do not establish that General Atomics' construction is incorrect. Although a claim interpretation that excludes a preferred embodiment is "rarely, if ever, correct", Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1374 (Fed.Cir.2005), here there is no dispute that the inhibition embodiment does not fall within the ' 717 patent's scope under either party's interpretation of the phrase "homocysteine conversion products."

FN8. Axis Shield also argues that the patents teach assessing SAH in this reaction, instead of assessing adenosine. *See* Green Decl., para. 18. While SAH could undoubtedly be monitored, given that it has a one-to-one relationship with homocysteine, the patents do not disclose using it as an analyte. The passage Axis Shield relies on states: "The SAH-hydrolase substrates used in the method of the invention may thus be SAH or adenosine or analogues and precursors thereof." '127 patent, 3 :56-58. This passage follows the description of the alternative SAH-hydrolase reactions, as described above, and discloses only that SAH or adenosine may be added to the sample. The Court does not read this passage as disclosing that SAH may be used as the analyte. Even if the Court were to accept Axis Shield's contention that the patents disclose using SAH as the analyte, it would agree with General Atomics that SAH would constitute a "homocysteine conversion product" because it is actually derived from homocysteine in the enzymic reaction, and that the embodiment is therefore consistent with General Atomics' construction.

Finally, Axis Shield also raises two other arguments that can be quickly disposed of. First, Axis Shield argues that General Atomics' construction is incorrect because it is inconsistent with the requirement that the analyte be "non-labelled." As General Atomics responds, however, the selection of a particular detection method is unrelated to the choice of which analyte to assess. *See* Borchardt Reply Decl., para. 13. While the Court's construction of "homocysteine conversion products" may render the invention more similar to prior techniques that utilized radioactive labeling, there is no requirement that the inventions use labeling; in fact, they specifically prohibit it. Second, Axis Shield argues that the use of the plural "homocysteine conversion products" indicates that the analyte may be any of the products of the reaction. The Court disagrees. Axis Shield's use of the plural is more easily explained by the existence of reactions in which homocysteine is converted into multiple products. *See* Aannestad Reply Decl., Exh. 20 at 2 (describing conversion of homocysteine and water into three products through the use of the homocysteinase enzyme).

Accordingly, the Court adopts General Atomics' proposed construction. The "homocysteine conversion products" must be products that actually derive from homocysteine in the enzymic reaction.

2. Literal Infringement

[17] It is undisputed that SAH, the analyte in General Atomics' assay, does not derive from homocysteine. Instead, SAH is derived only from SAM in the reaction. Thus, General Atomics' assay does not contain the claim limitation "assessing ... the homocysteine conversion products of the enzymic conversion of homocysteine by said enzyme."

Axis Shield argues, however, that even if the Court adopts General Atomics' proposed construction, there is still an issue of material fact regarding literal infringement of the claim. Specifically, Axis Shield argues that during the conversion of homocysteine to methionine in General Atomics' assay, homocysteine releases a single hydrogen ion. According to Axis Shield, if this hydrogen ion were to become bound to the SAH, then SAH would be derivative of the homocysteine and would therefore be a "homocysteine conversion product" even under General Atomics' construction of that phrase. Axis Shield therefore requests additional time to research the fate of the hydrogen ion in the General Atomics assay.

The Court cannot agree with Axis Shield's analysis. Even if the hydrogen ion were found to bond to the SAH, Axis Shield does not assert that this bonding occurs as part of the enzymic reaction. *See* Green Decl., para. 40-41. Rather, the ion would associate with the SAH after the enzymic reaction occurs, meaning that the SAH and associated hydrogen ion would not be a "product" of the enzymic conversion of homocysteine. Instead, they would be a product of a second reaction.

Accordingly, the Court finds that there is no issue of material fact regarding whether General Atomics' assay literally infringes the '127 and '717 patents.

3. Doctrine of Equivalents

[18] [19] [20] Axis Shield also asserts that General Atomics' assay infringes its patents under the doctrine of equivalents. "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 733, 122 S.Ct. 1831, 152 L.Ed.2d 944 (2002). The doctrine asks "whether the element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." Aquatex Indus., Inc. v. Techniche Solutions, 419 F.3d 1374, 1382 (Fed.Cir.2005) (quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608, 70 S.Ct. 854, 94 L.Ed. 1097 (1950)). "[T]he doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. It is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997).

[21] [22] As an initial matter, the Court notes that the PTO recently issued a notice of allowance for General Atomics' patent application that covers its assay. *See* Aannestad Decl., Exhs. 10, 14. In considering the patentability of General Atomics' invention, the PTO considered both the ' 127 patent and the '717 patent. Id. at Exh. 11. When the PTO grants a patent that covers an accused product with knowledge of the asserted patents, a court may consider it as evidence that the product is not equivalent to the invention disclosed by the asserted patents. *See* Hoganas AB v. Dresser Indus., 9 F.3d 948, 954 (Fed.Cir.1993) ("[T]he PTO must have considered the accused product to be nonobvious with respect to the patented composition. Accordingly, the issuance of that patent is relevant to the equivalence issue."). While not conclusive, General Atomics' recent patents support its argument that its assay does not infringe under the doctrine of equivalents.

General Atomics' main argument against the doctrine of equivalents is that a finding of equivalence would render meaningless the limitation in the Axis Shield patents that the assessed analyte must be a conversion product derived from homocysteine. *See* Freedman Seating Co. v. American Seating Co., 420 F.3d 1350, 1358(Fed.Cir.2005) ("[A]n element of an accused product or process is not, as a matter of law, equivalent to a limitation of the claimed invention if such a finding would entirely vitiate the limitation."). This appears to be correct; if General Atomics' assay were found to infringe under the doctrine of equivalents, then the limitation that the analyte be a "homocysteine conversion product" would be meaningless. Axis Shield has not responded in any way to General Atomics' argument. Rather, it argues at a high level of generality that the SAH in General Atomics' assay is equivalent to the "homocysteine conversion product" in its patents because both measure homocysteine by measuring a product of the homocysteine conversion reaction that has a one-to-one correspondence with the homocysteine in the test sample. The Court finds that accepting Axis Shield's argument would entirely vitiate the claim limitation "homocysteine conversion product of the enzymic conversion of homocysteine." Accordingly, the Court finds that the SAH in General Atomics' assay is not equivalent to a "homocysteine conversion product."

C. Conclusion

In the language of the patents at issue, the General Atomics assay uses SAH as its analyte. SAH is neither a "homocysteine co-substrate" for the enzymic reaction in General Atomics' assay, nor a "homocysteine conversion product" of the reaction or its equivalent. Accordingly, summary judgment of noninfringement is appropriate.

CONCLUSION

For the foregoing reasons and for good cause shown, the Court hereby GRANTS General Atomics' motion for summary judgment of noninfringement (Docket No. 43).

IT IS SO ORDERED.

N.D.Cal.,2006.
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